

PRODUCT CERTIFICATE

Product: Contec HydroKlean
Product Code: SBT34HK6IR
Product Description: Sterile filled, 6% stabilized Hydrogen Peroxide in water for injection 1L Trigger Spray
Batch Number: 200401387
Manufacture Date: APR / 21 / 2020
Expiry Date: APR / 2022

ANALYSIS

Test	Specification	Results
Color:	Colorless	Complies
Clarity:	Clear	Complies
Filtration:	Filtered to 0.2 microns	Complies
Endotoxins:	<0.25 EU/ml	Complies
SG at 20°C:	1.021 – 1.025	1.023
Concentration of H ₂ O ₂ :	6.0% - 6.9%	6.8%

Manufactured product via a Quality System certified to ISO 9001:2015, tested in accordance with documented quality procedures and approved when required specifications are met.

STERILITY

Sterility test number: 0000529914, 0000529915, 0000529916

Sterility test result: No evidence of microbial growth

Test method as described in the current edition of the European Pharmacopoeia.

Name: 1: Lee Rodgers 2: John Gray
Position: 1: Snr. Quality Technician 2: Quality Manager

Date: 1: 29 Jun 20 2: 29 Jun 20

Authorized Signature:
For and on behalf of Contec Inc

1:

2:

COA023 Rev4

Manufactured by:
Contec Cleanroom (UK) Ltd
Unit 6A Wansbeck Business Park
Ashington
UK

America
Contec Inc
P.O.Box 530
Spartanburg SC
USA

Europe
Contec Inc
ZI du Prat RP 3707
56037 VANNES
France

China
Contec Cleanroom Technology (Suzhou) Co. Ltd
No. 17 Longyun Road
Suzhou 215024
China

www.contecinc.com
infoeu@contecinc.com

STERIS: Gamma Certificate Of Processing

Prepared for: CONTEC CLEANROOM UK LTD (8250)

Gamma Process Run ID: 2173-10148A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
PRIMARY PACKAGING 1L GAPLAST DV4781	SBT34HK61R, 200401387	32	Case

Validation Reference Number: 4781

Processing Run Start Date: 29-Apr-20 09:03 PM

Processing Run End Date: 30-Apr-20 03:30 AM

Specified Dose Range (kGy):	25.0 - 95.0	Calculated Min Dose (kGy):	32.2
Reference Dose Range (kGy):	26.1- 88.8	Calculated Max Dose (kGy):	36.8

PO Number: 108780

Gamma Process Run Approval & Signed By : Bhavya Ramisetty

Rev : 2

Bk 04. May. 2020; 08:08AM

Operating facilities are in compliance with applicable regulations providing services under a certified ISO 13485 quality system and processing in accordance with STERIS practices and procedures.

Processing Location

Synergy Health Sterilisation UK
Limited, a STERIS Company
Brunel Close
Drayton Fields Industrial Estate
Daventry
Northants
NN11 8RB
Phone: + 44(0) 1327 706 111